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EXAMINER

RADEMACHER, MARK A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3761

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/070,933

Applicant(s)

SEPPALA, KARI

Examiner

Mark Rademacher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-14 is/are rejected.
- 7) ☒ Claim(s) 1-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 371 and 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Specification*

2. The disclosure is objected to because of the following informalities: It is the examiner's position that applicant has evoked sixth paragraph, means-plus-function language to define applicant's invention. Therefore the examiner requires the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))
3. Appropriate correction is required.

### *Claim Objections*

4. Claims 1-15 are objected to because of the following informalities: It is the examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define applicant's invention. Therefore the examiner has objected to the claims for the reasons set forth above in the objection to the specification.

5. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

7. A person shall be entitled to a patent unless –

8. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US patent no.

5,201,308 to *Newhouse* or US patent no 5,447,151 to *Bruna et al* or published international application WO 92/18188. ('188 publication).

10. Each of the above-cited prior art documents discloses a powder inhaler comprising (i) a powder container, (ii) an air channel through which air can be drawn via a mouthpiece, (iii) a metering member having a dosing recess, and movable between an inhalation position and a filling position, (iv) means for displacing the metering member between the filling and inhalation positions and (v) a closure element adapted to plug the air channel around the metering member in a substantially water-proof manner, so as to protect the air channel around the metering member from moisture when the metering member is in the inhalation position.

11. In each case elements (i) through (iv) are apparent from the FIGS of the cited documents.

12. The applicant specifies that the “substantially waterproof” plugging functionality of the closure member is to prevent entry of water via the air channel in an amount that would have a detrimental effect on the measuring and discharging properties of the device”. See the third full paragraph on page 5 of the present disclosure. Accordingly, the examiner’s position is that

plugging the passage in a “substantially waterproof” manner merely means that the passage is sealed to the extent to allow reliable measurement and discharge of medicament. Because all of the documents cited above profess reliable measurement and discharge of medicaments, it is the examiners position that any closure element disclosed therein inherently meets the functional limitations recited in the closure member clause of claim 1.

13. For example, the ‘188 publication discloses a closure member in the form of the walls of the apertures (8), which seal against the shaft (3) to seal the air channel (10) around the metering member in a substantially waterproof manner. See the bottom of page 8 of the ‘188 publication.

14. In the *Bruna et al* and *Newhouse* disclosures, the closure member takes the form of a one-way valve that closes off the air passage through which air is drawn until such time as inhalation begins. That is the air channel is plugged when the metering member is in the filling position and open when the metering member is in the inhalation position. *Bruna et al* disclose a valve (85) having the capability recited, and *Newhouse* discloses a one-way flap valve (44) having the same capability.

15. Claims 2, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by the ‘188 publication. The closure means, i.e., walls around aperture (8), communicates with the actuator means (button 11) in that the actuator means (11) is connected to the metering rod (3), which interacts with the flexible walls around the aperture (8) to alternately plug and open the airway around the metering rod.

16. In addition, the invention disclosed in the ‘188 publication includes a metering member (3) that is in the form of an axially moveable metering rod equipped with a dosing recess (5) and that extends into the interior of the powder container (1). See, e.g., FIGS 1 and 14.

17. Claims 3 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by the *Bruna et al* patent.
18. In FIG 9 *Bruna et al* disclose a powder inhaler including all of the features recited in claim 3 including a closure element (85) and a sealing means in the form of a shoulder (unnumbered) in the box (1) against which the closure element is secured to plug the air channel in a substantially water proof way.
19. The device disclosed by *Bruna et al* includes a metering member is in the form of a metering rod (81) equipped with recess (204). The metering rod (81) extends into the powder container (202). The metering rod (81) is connected to an actuating means in the form of a depressible device cover (pusher 2).
20. See also the inhaler shown in FIG 10.
21. Claims 3 is rejected under 35 U.S.C. 102(b) as being anticipated by the *Newhouse* patent.
22. *Newhouse* discloses all of the features recited in claim 3 including a closure member (44) and a sealing means in the form of spider (46) against which the flap valve (44) seats in order to secure the substantially water-proof plugging of the air channel by the closure element.

***Claim Rejections - 35 USC § 103***

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  24. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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25. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 5447151 to *Bruna et al* in view of published international application no. WO 90/02576 (the '576 publication).

26. *Bruna et al* disclose powder inhalers having all of the features recited in claim 12 except a second sealing means for providing substantially water-proof sealing between the actuating means and the inhaler body, while allowing movement of the actuating means in relation to the inhaler body.

27. The '576 publication discloses a sealing means (protective barrier 19) that provides substantially waterproof sealing between the inhaler body and the actuating means (canister 15). See FIG 4.

28. At the time the invention was made it would have been obvious to one with ordinary skill in the art to modify the inhalers disclosed by *Bruna et al* to include an additional sealing means as taught in the '576 publication between the actuating means (pusher 2) and the inhaler body (box 1) in order to protect the dose delivering mechanism from being impacted by moisture from a user's breath. See page 9, lines 3-5.

29. Although the publication does not expressly disclose that the seal (19) comprises corrugated walls, at the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify the inhaler disclosed by *Bruna et al* to include a seal comprising corrugated walls. The applicant has not disclosed that corrugated walls provide an advantage over an elastic seal, is used for a particular purpose, or solves a stated problem. One with ordinary skill in the art would have expected the applicant's invention to perform equally well with an elastic seal (19) as taught in the '576 publication since such as seal is equally

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capable of allowing relative movement between the inhaler body and the actuating means, while providing a substantially waterproof seal.

30. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the '188 publication.

31. Although the '188 publication does not explicitly disclose sealing means in addition to the walls (8) around the aperture through which the metering member slides, it is suggested that separate shaft sealing means may be employed in some situations. See the paragraph bridging pages 8 and 9.

32. At the time the invention was made it would have been obvious to one with ordinary skill in the art to modify the device disclosed in the '188 publication to include additional sealing means around the in order to better ensure a substantially waterproof seal around the metering member.

#### ***Allowable Subject Matter***

33. Claims 4-8 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Contact Information***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR   
March 31, 2003

  
GLENN K. DAWSON  
PRIMARY EXAMINER

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***CHANGE OF ADDRESS FOR THE COMMISSIONER FOR PATENTS***

As of May 1st, 2003 the correspondence address for the Director of the USPTO and the Commissioner for Patents will be:

PO Box 1450  
Alexandria, VA 22313-1450

See, Federal Register, Vol. 68, No. 57, March 25, 2003.